UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,233	01/04/1999	KEITH HENRY STOCKMAN CAMPBELL	SP-01-US-DIV-1	2711

76392 7590 01/04/2010

LAW OFFICE OF SALVATORE ARRIGO
1050 CONNECTICUT AVE. NW
10TH FLOOR
WASHINGTON, DC 20036

EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	

NOTIFICATION DATE	DELIVERY MODE
01/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SAL@ARRIGO.US

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/225,233
Filing Date: January 04, 1999
Appellant(s): CAMPBELL ET AL.

Salvatore J. Arrigo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 8, 2009 appealing from the Office action mailed November 10, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appeal filed June 6, 2006 in application Ser. No. 09/658862; and

Appeal filed June 6, 2006 in the present application, 09/225233.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct. Please note the Terminal Disclaimers filed May 8, 2009 were proper. Thus the obviousness type double patent rejection made in the office action mailed November 10, 2008 is withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Sims et al. Production of Calves by Transfer of Nuclei from Cultured Inner Cell Mass Cells. June 1993, Vol. 90, pp. 6143-6147.

McLaughlin et al. In Vitro Embryo Culture in the Production of Identical Merino Lambs by Nuclear Transplantation. Reproduction Fertility Development. 1990,. Vol. 2, pp. 619-622.

Prather et al. Nuclear Transplantation in Early Pig Embryos. Biology Reproduction. Vol. 41, No. 3, pp. 414-418.

Yong et al. Nuclear Transplantation in Goats. Theriogenology. January 1991, Vol. 35, No. 1, pp. 299.

Zinn. Influence of Processing on the Comparative Feeding Value of Barley for Feedlot Cattle. J. Animal Science, 1993, Vol. 71, pp. 3-10.

Aldrich et al. The Effects of Endophyte-Infected Tall Fescue Consumption and Use of a Dopamine Antagonist on Intake, Digestibility, Body Temperature, and Bolld Constituennts in Sheep. J. Animal Sci., 1993, Vol. 71, pp. 158-163.

Matte et al. Effect of Long-Term Addition of Folic Acid on Folate Status, Growth Performance, Puberty Attainment, and Reproductive Capacity of Gilts. J. Animal Sci., 1993, Vol. 71, 151-157.

Ortega-Reyes et al. Experience with Blackbrush Affects Indigestion of Shrub Live Oak by Goats. J. Animal Sci., 1993, Vol. 71, pp. 3380-383.

*Flisikowski et al. New Polymorphism in the Bovine *STAT5A* Gene and Its Association with Meat Production Traits in Beef Cattle. Animal Science Papers and Reports, 2003, Vol. 21, pp. 147-157.

*Koehler at al. Replacement of Bovine Mitochondrial DNA by a Sequence Variant Within One Generation. Genetics, 1991, Vol. 129, pp. 247-255.

*Abhyankar et al. “Off-Anlge Iris Recognition Using Bio-Orthognal Wavelet Network System”, in Automated Identification Advanced Technologies, 2005, Fourth IEEE Workshop, page 239-244 (http://ieeexplore.ieee.org/xpls/abs_all.jsp?arnumber=1544431&tag=1).

*F. Schmidt,. "Chapter 16 - RNA:Structure, Transcription and Processing," in Textbook of Biochemistry with Clinical Correlations, Thomas Devlin, ed. John Wiley & Sons, New York, 1997, page 678.

*Bourchard et al. "Analyzing Genomic DNA Discordance Between Monozygotic Twins" Chapter 2.2.5 in Handbook of Molecular Genetic Techniques for Brain and Behavior Research, . W.E. Cuscio and R.T. Gerlai, eds. (*Techniques in the Behavioral and Neural Sciences, Vol. 13)*, Elsevier Science BV, 1999, pages 237-254.

*Indicates references relied upon to rebute Appellant's arguments in the Appeal Brief. These references are newly cited.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 155-159 and 164 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for reasons set forth in the Examiner's Answer mailed September 11, 2006, the BPAI Decision, mailed January 30, 2008 and the office action mailed November 2, 2008. Claims 155-159 and 164 are drawn to a live born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs and goats. However, the claimed mammals do not sufficiently distinguish over pre-existing cattle, sheep, pigs and goats. Neither the

claims nor the specification point out any structural or phenotypic differences that distinguishes the claimed cloned mammals from the pre-existing mammal. The method of making the mammals does not imbue any new or novel characteristic to the cloned mammals nor does the method imbue a new use to the mammals claimed. Further, the claims clearly state that the clone is a copy of a pre-existing mammal. Hence, the mammal as claimed is indistinguishable from the mammal as found in nature. Thus, the cloned nonhuman mammals of the claims is not seen as being “new” as required by 35 U.S.C. § 101.

It is well known and accepted that patentability is precluded for certain subject matter, products of nature, being one of them. The claimed cloned nonhuman mammals were, as disclosed in the specification, indeed, produced by a method that has the hand of man associated with it. However, the question raised under 35 U.S.C. § 101 relates to the patentability of subject matter that occurs in nature, is a copy of a product of nature, but the copy was created by the hand of man. Does the hand of man extend through the method to the product?

The actuality is, Appellant developed a method whereby a nonhuman mammalian embryo can be made by an in vitro method, and the embryo is transferred to a surrogate female nonhuman mammal. The surrogate female nonhuman mammal actually “makes" a cloned nonhuman mammal from Appellant's in vitro produced embryo. By virtue of "employing" the naturally occurring female to produce the clone, a copy or replica of a prior existing mammal, the resultant mammal is a product of nature. In this regard, a cattle, sheep, pig or goat produced by IVF is a product of nature, even

though the embryo was made in vitro. There are no structural differences between a cattle, sheep, pig or goat produced by mating, IVF or cloning, at least none are disclosed in specification or recognized in the art.

Since there is no alteration of the cloned nonhuman mammals claimed versus nonhuman mammals produced by other means, cloned a cattle, sheep, pig or goat cannot be distinguished from its IVF or mating produced counterpart. Without a distinction, each cloned cattle, sheep, pig or goat is a product of nature. The cloned mammals are copies or replicas of pre-existing nonhuman mammals and thus are not "new" inventions.

To reiterate, the cloned nonhuman mammals of the claim have not been described by the specification or the art as having any distinguishing effect by the hand of man method of making them. Thus, while Appellant has a method that exhibits clearly the hand of man, it is not clear that the mammal products of the method exhibit the hand of man. Appellant, it would appear has invention a new method to produce a product of nature, similar to the IVF situation. There is no case law, other decisional law or policy that directs the patentability of fundamentally wild-type cattle, sheep, pigs and goats produced by in vitro methods.

Thus, as the claims are to nonstatutory subject matter, the claims are not patentable.

35 U.S.C. § 102/103

In the art rejections below, the rejections have been made under 35 U.S.C. § 102/103. The phrase "live-born clone of a … mammal" imbues the method by which the clone was made, nuclear transfer.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skills in the art to which said subject matter pertains. patentability shall not be negatived by the manner in which the invention was made.

Claims 155, 156 and 164 (cattle) remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147 for reasons set forth in the office action mailed November 2, 2008.

Sims teaches cloned bovines (page 6146, col. 1, parag. 2, lines 6-11). As the presently claimed cloned cattle do not exhibit a novel structural or functional difference from those described in Sims, Sims anticipates the claimed invention. In the alternative, the claimed cattle is obvious over Sims because there is no perceived structural or functional difference between the claimed cattle and the bovines of Sims. Thus, Sims either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the Appellant and the prior art are the same, the Appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima *facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 157 and 164 (sheep) remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McLaughlin et al (1990) Reproduction Fertil. Develop. 2, 619-622 for reasons set forth in office action mailed November 2, 2008.

McLaughlin teaches cloned sheep (page 620, parag. 2-5, and page 621, parag. 1). As the presently claimed cloned sheep do not exhibit a novel structural or functional difference from those described in McLaughlin, McLaughlin anticipates the claimed invention. In the alternative, the claimed sheep is obvious over McLaughlin because there is no perceived structural or functional difference between the claimed sheep and the sheep of McLaughlin. Thus, McLaughlin either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the Appellant and the prior art are the same, the Appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima *facie* case can be rebutted by evidence showing that the prior art

products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 158 and 164 (pigs) remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Prather et al (1989) Biology of Reproduction 41, 414-418 for reasons set forth in the office action mailed November 2, 2008.

Prather teaches a cloned pig (page 415, col.1, parag. 1 to page 416, line 8, and page 416, col. 2, lines 8-10). As the presently claimed cloned pigs do not exhibit a novel structural or functional difference from the pig described in Prather, Prather anticipates the claimed invention. In the alternative, the claimed pig is obvious over Prather because there is no perceived structural or functional difference between the claimed pigs and the pig of Prather. Thus, Prather either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the Appellant and the prior art are the same, the Appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima *facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 159 and 164 (goats) remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yong et al (1991) Theriogenology 35, page 299 for reasons set forth in office action mailed November 2, 2008

Yong teaches cloned goats by nuclear transfer of the reconstituted goat embryos (parag. 2 and Table). As the presently claimed cloned goat does not exhibit a novel structural or functional difference from the goat described in Yong, Yong anticipates the claimed invention. In the alternative, the claimed goat is obvious over Yong because there is no perceived structural or functional difference between the claimed goat and the goat of Yong. Thus, Yong either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the Appellant and the prior art are the same, the Appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima *facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

The rejections below establish the claimed cloned cattle, sheep, goat and pig are not patentably distinct from cattle sheep, goat and pig produced by sperm fertilization of an ovum.

Claims 155, 156 and 164 (cattle) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zinn (1993) J. Animal Science, Vol. 71, pp. 3-10 for reasons set forth in the office action mailed November 2, 2008.

Zinn teaches cross-bred steers, cattle (page 3, col. 2, parag. 1, line1 to page 4, col. 1, line 3). As the presently claimed cloned cattle do not exhibit a novel structural or functional difference from those described in Zinn, Zinn anticipates the claimed invention. In the alternative, the claimed cattle is obvious over Zinn because there is no structural or functional difference between the claimed cattle and the bovines of Zinn. In a side-by-side comparison, the ordinary artisan would not differentiation between the cattle claimed and those or Zinn. The specification does not disclose any structural or physical features that would distinguish between the cattle claimed and those known in the art at the time of filing. Appellant should note those physical and structural differences that distinguish the claimed cattle from those of Zinn. The specification does not provide for such, and no such differences are observed in the cattle are noted in the specification. Thus, Zinn either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the Appellant and the prior art are the same, the Appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ

563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 157 and 164 (sheep) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aldrich et al. (1993) J. Animal Sci., Vol. 71, pp. 158-163 for reasons set forth in the office action mailed November 2, 2008.

Aldrich teaches young sheep or lambs (page 158, col. 2, parag. 2, lines 1-3). As the presently claimed cloned sheep do not exhibit a novel structural or functional difference from those described in Aldrich, Aldrich anticipates the claimed invention. In the alternative, the claimed sheep is obvious over Aldrich because there is no structural or functional difference between the claimed sheep and the sheep of Aldrich. In a side-by-side comparison, the ordinary artisan would not differentiation between the sheep claimed and those of Aldrich. The specification does not disclose any structural or physical features that would distinguish between the sheep claimed and those known in the art at the time of filing. Appellant should note those physical and structural differences that distinguish the claimed sheep from those of Aldrich. Thus, Aldrich either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the Appellant and the prior art are the same, the Appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ

563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 158 and 164 (pigs) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matte et al. (1993) J. Animal Sci., Vol. 71, 151-157 for reasons set forth in the office action mailed November 2, 2008.

Matte teaches female pigs or gilts (page 151, col. 2, parag. 1, lines 1-2). As the presently claimed cloned pigs do not exhibit a novel structural or functional difference from the pigs described in Matte, Matte anticipates the claimed invention. In the alternative, the claimed pig is obvious over Matte because there is no perceived structural or functional difference between the claimed pigs and the pig of Matte. In a side-by-side comparison, the ordinary artisan would not differentiation between the pigs claimed and those of Matte. The specification does not disclose any structural or physical features that would distinguish between the pigs claimed and those known in the art at the time of filing. Appellant should note those physical and structural differences that distinguish the claimed pigs from those of Matte. Thus, Matte either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the Appellant and the prior art are the same, the Appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ

563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 159 and 164 (goats) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ortega-Reyes et al. (1993) J. Animal Sci., Vol. 71, pp. 3380-383 for reasons set forth in the office action mailed November 2, 2008.

Ortega-Reyes teaches goats (page 380, col. 2, parag. 2, lines 1-2). As the presently claimed cloned goat does not exhibit a novel structural or functional difference from the goat described in Ortega-Reyes, Ortega-Reyes anticipates the claimed invention. In the alternative, the claimed goat is obvious over Ortega-Reyes because there is no perceived structural or functional difference between the claimed goat and the goat of Ortega-Reyes. In a side-by-side comparison, the ordinary artisan would not differentiation between the goat claimed and that of Ortega-Reyes. The specification does not disclose any structural or physical features that would distinguish between the goat claimed and those known in the art at the time of filing. Appellant should note those physical and structural differences that distinguish the claimed goat from that of Ortega-Reyes . Thus, Ortega-Reyes either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the Appellant and the prior art are the same, the Appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*,

778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

(10) Response to Argument

Appellant argues the Examiner and the Board of Appeals erred in interpreting the claims as product by process (Appeal Brief filed September 9, 2009, page 17, parag. 3). Appellant argues whereas the claims can only be made by cloning the parent mammal, a similar argument can be made for any product made by human intervention. (Brief, page 17-18, bridg. sent.). Appellant argues because a method of cloning requires cloning, does not make the claimed invention product-by-product (Brief, page 18, lines 4-6). Appellant states the term "clone" should be viewed as a structural limitation (Brief, page 18, line 6). Appellant argues the term "clone" implies a structural limitation because the clone must be a "structural" copy of the parent that is the clone must have the same genetic complement as the donor animal (Brief, page 18, parag. 1). These arguments are not persuasive

Appellant points directly to the major divide between the examiner and appellant. The adjective clone is not seen as providing any structural features to the mammal produced by a cloning method that is nuclear transfer. To define the mammal as a clone immediately gives the skilled artisan an image as to how the mammal was made, not a structural feature of the mammal. The mammal is not described by the specification as having any structural difference from other mammals of the same species.
In reference to the "same genetic complement," the specification does not use the term, and Appellant's use of the term is not clear. The art at the time of filing defines "genetic

complement" as the DNA content of a cell ("The primary information store of a cell is it genetic complement, that is, its DNA"(Develin, page 678, 16.1, line 1.) Further, the art shows that mammals of the same species can have the same genomic DNA and mitochondrial DNA restriction fragment length polymorphism (RFLP) or restriction fragment length. Flisikowski shows out of 8 bovines, 3 SSCP patterns (single-strand conformation polymorphism) or genotypes were found for the STAT5A gene. This data shows that there were not 8 genotypes for the STAT5A gene, but 3 genotypes. Certain of the bovines shared the same STAT5A genotype: 3 bovines had genotype 1; 4 had genotype 3 and 1 had genotype 3 (Flisikowski, page 150, figure 1). Thus, individual bovines produced by sexual reproduction had the same "structure" giving it the same genetic complement. Also, in analyzing mitochondrial DNA, Koehler showed several separate Holsteins having the same mitochondrial genotype (Koehler, page 249, Figure 2A). The mitochondrial DNA labeled L-5602 is indistinguishable from one another. Each sample was isolated from leukocytes of individual bovines. This data clearly shows the L-5602 bovines possessed the same "structure" and the "same genetic complement." There is no guidance in the specification as to determining the "same genetic complement." In fact the term is not used at all in the specification. Thus, the data of Flisikowski et al. and Koehler et al. refute appellant's allegation that a clone and the nuclear donor are distinct and can never be genetically the same as another mammal of the same species. This is simply scientifically false. Mammals sexually produced can have the same genetic complement as shown by the art. These data indicate multiple mammals within a species can have the "same genetic complement." Thus having the

"same genetic complement" does not provide evidence of a clone and donor, separate from other members of the same species. This brings us back to the quandary with appellant's claims. The clones as claimed are no different from the wild-type mammals of the same species found in nature. Appellant has found a new method of making naturally occurring products but the products are old and cannot be distinguished from the old products.

Appellant argues claims are viewed by the court as having structural limitations instead of process limitations, citing *In re Garnero* (Brief, page 18, parag. 2, lines 1-2). This argument is not persuasive.

The claim on appeal in Garnero was: 1. A composite, porous, thermal insulation panel characterized by dimensional stability and structural strength consisting essentially of expanded perlite particles which are interbonded one to another by interfusion between the surfaces of the perlite particles while in a pyroplastic state to form a porous perlite.

None of the terms of the claims imply method such a "clone." Simply put, the art at the time of filing recognized an animal clone as an animal produced by nuclear transfer.

Appellant argues the Federal Circuit in *3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365 decided words of limitation that can connote with equal force a structural characteristic of the product or process of manufacture are commonly and by default interpreted in their structural sense, unless the patentee has demonstrated otherwise (Brief, page 19, parag. 1). Appellant concludes the term "clone"

in the present claims should be construed as a structural limitation (Brief, page 19, parag. 1). This argument is not persuasive.

The court in *3M Innovative Properties Co.* found that the district court had erred by introducing a process limitation that is not present in the specification into the reading of the claimed invention. This, however, is not the situation here. "Cloning" by somatic cell nuclear transfer is the only method for producing the claimed cloned mammals disclosed. The Examiner and the Board have not transferred a meaning not clearly supported by the specification. Thus, given the present specification's definition of "cloning" as a method for producing a copy or replica of a known mammal, the interpretation of the claims by a product by process in correct.

Appellant argues the presence of a process limitation, such as clone, does not convert the claim to product-by-process, citing *Fromson v. Advance Offset Plate, Inc* (Brief, page 19, parag. 2, lines 1-4). Likewise, Appellant argues, the term "clone" in the present claims does not convert them to product-by-process claims (pages 19-20, bridg. sent.). This argument is not persuasive.

The court in Fromson made the statement in a review of a combination of old products under 35 U.S.C. § 103, the issue here is 35 U.S.C. § 101.

Appellant argues the relevant distinction between statutory and non-statutory invention is between products of nature and human-made inventions, citing *Diamond v. Chakrabarty* (Brief, page 20, parag. 1). Appellant sates their clones must be made by man and therefore are statutory (Brief, page 20, parag. 1, lines 5-6). Appellant argues their clones are never found in nature, and thus the claimed clones are non-naturally

occurring product of human ingenuity (Brief, page 20, parag. 2, lines 1-4). These arguments are not persuasive.

While appellant has argued the products are produced by a new method, cloning, appellant does not describe any differences between the resulting products. The issue here is not the method of producing the mammals. Nuclear transfer methods are recognized as having the "hand of man." The issue here is the products of nuclear transfer. Do the products have the "hand of man." A cattle, sheep, pig or goat produced by somatic cell nuclear transfer is indistinguishable from the same mammal produced sexually. They have the same metabolic and physiologic functions. They have the same uses. Nothing pertaining to the product has changed. While a clone may be produced asexually, the product of the method, it is nonstatutory because it cannot be distinguished from the prior existing mammal (cattle, sheep, pigs and goats). There is no discernable difference that lends a patentable distinction between the clone and the pre-existing mammal, although the methods of producing them are different. Claim 155 clearly state the clone is of a pre-existing mammal. Thus, the claimed mammals are products of nature, just as a mammal produced by IVF would be regarded as a product of nature. Further, the fact that appellant admits the claimed clones are clones of pre-existing mammals is evidence that the mammals exist or existed without the hand of man. Thus, the criteria of Allen, as stated by Appellant, is provided. With regard to the "hand of man" in Chakrabarty, in a side-by-side comparison with the pre-existing mammal, the cloned mammals could not be seen to have any evidence of a "hand of man." Having the same chromosomal complement of the pre-existing mammal lends

further credence to the clones being non-statutory)See Appeal Brief filed June 16, 2006, page 9, lines 3-5). If the clones are the same as what appellant would agree is a product of nature, a mammal produced by sexual reproduction, then the mammals produced by nuclear transfer must also be products of nature. While there is evidence of the hand of man in methods of nuclear transfer, there is no evidence of the hand of man in the presently claimed live-born clones.

Appellant argues the examiner is in error in stating there is no difference between mammals produced by IVF, cloning or mating as only a cloned mammal has the same genetic complement as its parent (Brief, page 20-21, bridg. sent). Mammals produced by IVF and mating have a genetic complement that is a mixture of the genetic complement of two parents (Brief, page 21, lines 2-3). These arguments are not persuasive.

Flisikowski shows out of 8 bovines, 3 SSCP patterns or genotypes were found for the STAT5A gene. This data shows that there were not 8 genotypes for the STAT5A gene, but 3 genotypes. Certain of the bovines shared the same STAT5A genotype: 3 bovines had genotype 1; 4 had genotype 3 and 1 had genotype 3 (Flisikowski, page 150, figure 1). The relevancy for this prosecution is by analysis of the STAT5A gene, one could not distinguish a clone of a cow with genotype 1 from another herd member with genotype 1. Also, in analyzing mitochondrial DNA, Koehler showed several separate Holsteins having the same mitochondrial genotype (Koehler, page 249, Figure 2A). The mitochondrial DNA labeled L-5602 is indistinguishable from one another. Each sample was isolated from leukocytes of individual bovines. This data clearly shows

none of the L-5602 bovines can be distinguished from one another, and could not be determined if any of these bovines were a clone of another bovine. The genetic analysis of mitochondrial DNA is insufficient in Koehler to distinguish any bovine from its herd-mate, progeny or clone. The genetic complement is not a signature of one distinct mammal. In other words, individual identity cannot be ascertained by genetic analysis if multiple mammals have the same genetic complement, which is shown by Flisikowski et al and Koehler et al.

Appellant argues the examiner is in error for stating the claimed mammals are products of nature because a mammal is used in the cloning process (Brief, page 21, parag. 1, lines 1-3). Appellant argues, by comparison, that all recombinant biological products would be considered "products of nature" and cites an example of producing a protein in a bacterial cell (Brief, page 21, parag. 1, lines 6-8). Appellant argues a copy of a pre-existing thing is statutory subject matter (Brief, page 21-22, bridg. sent.). Appellant argues the Federal Circuit defines statutory subject matter very broadly, citing *In re Alappat* (Brief, page 22, lines 1-2). Appellant argues the Supreme Court and the Federal Circuit have defined categories of invention that are not statutory: 1) abstract ideas; 2) natural phenomena; and 3) laws of nature (Brief, page 22, parag. 1, lines 2-7). Appellant argues the claimed cloned mammals do no not fall into any of these categories as it is neither an abstract idea nor a law of nature, and since nature does not produce clones, the clones cannot be natural phenomena (Brief, page 22, parag 1, line 8 to page 23, line 3). These arguments are not persuasive.

Using a purified recombinant protein X verses a naturally occurring protein X, purified from a tissue source, as an example, the recombinant protein may have an issue under 35 U.S.C. § 101 if the recombinant protein X and the protein X purified from a tissue source could not be distinguished. A product of nature produced by another method remains a product of nature.

Appellant argues the term "new" in 35 USC 101 does not dictate an independent requirement of novelty or non-obviousness distinct from the requirements of 35 USC 102 and 103 as found by the Federal Circuit in *In re Bilski* (Brief, page 23, parag. 3, lines 1-3). This argument is not persuasive.

The court in Bilski stated "Although §101 refers to "new and useful" processes, it is overall "a general statement of the type of subject matter that is eligible for patent protection 'subject to the conditions and requirements of this title.'" *Diehr*, 450 U.S. at 189 (quoting §101). As the legislative history of §101 indicates, Congress did not intend the "new and useful" language of §101 to constitute an independent requirement of novelty or non-obviousness distinct from the more specific and detailed requirements of §§102 and 103, respectively. *Diehr*, 450 U.S. at 190-91." The present rejection is based on the concept that appellants claimed clones are not "new" because they are copies of old mammals. While the analysis took a novelty/obvious bend, there is no requirement in the present rejection under 35 U.S.C. § 101 that the mammals be "new" in terms of statutory. The mammals are old because they are non-statutory products of nature. None of the case law cited by appellant addresses the issue of producing an old, non-statutory product by a new method, and the effect of the new method on the non-

statutory nature of the product. The question remains does a new method of making an old, non-statutory product make the old, non-statutory product now statutory. Appellant would say yes. The examiner would say no because the method does not make a new mammal. Similarly, a wild-type mammal produced by IVF is not going to be patentable over a wild-type mammal produced by sexual reproduction because the method produces the non-statutory product. Both the method of IVF and the method of nuclear transfer (cloning) have the hand of man, but the products have not been altered with regard to the hand of man. Appellant's argues the clone has the same genetic complement as the donor mammal and the sexually produced mammals have a mixed genetic complement is not valid. The clone is perpetuating the mixed genetic complement of the clone, and evidence is presented that genetic complements are not a signature of a clone and its donor. Mammals produced by sexual reproduction can have the same genetic complement. As outlined above by Flisikowski et al. and Koehler et al.

Appellant argues the claimed cloned mammal is patentable over the donor mammal in that the donor mammal does not anticipate the clone (Brief, page 24, parag.1, lines 1-3). Appellant argues the Board in the previous decision (mailed January 30, 2008) that the term "clone" did not mean an exact copy because of environmental factors (Brief, page 24, parag. 1, lines 3-8). Appellant argues the Board stated the clone and the parent will occupy a different space and time from one another and have phenotypic differences (Brief, page 24, parag. 1, lines 8-10). This argument is not persuasive.

Appellant fails to note that inspite of the above statements by the Board in the previous appeal decision, the BPAI found the claimed clones to be non-statutory. Appellant argues anticipation can only be found when the reference discloses exactly what is claimed and anticipation cannot be shown when the prior art teaches substantially the same invention as that claimed (Brief, page 25, parag. 1, lines 1-7). Appellant argues the specification indicates the clone is not identical to its parent (Brief, page 26, parag. 1,lines 1-3). Appellant continues by explaining the specification meant that the claimed clone would have the same nucleus or chromosomal complement as the parent, but the clone and the parent would be different because a different oocyte is used for each clone (Brief, page 26, parag. 1, lines 3-6). Appellant argues the use of different oocytes causes the clone and its parent to be non-identical (Brief, page 26, parag. 1, lines 6-7). Appellant argues the evidence provided by the office during prosecution shows the clone and its parent are not identical: the clone and parent may vary phenotypically due to environmental or uterine factors; differences in mitochondrial DNA may contribute to differences between a clone and its parent; the clone and the parent will have differences in iris pigmentation and a clone and its parent will have behavioral differences (Brief, page 26, parag. 1, line 1 to page 27, line 5). These arguments are not persuasive.

The art does disclose exactly what is claimed. This is supported by the teachings of Flisikowski et al and Koehler which show cows produced sexually have the same genetic complement at least one allele and same mitochondrial DNA genetic complement . Appellant has not provided any evidence that the mammals claimed and

those of the art have different genetic complement. If they do have genetic complement, what does not mean? They are still the “same”: mammals physiologically and functionally. Different genomes, where the differences are silent, not affecting the art recognized function of the mammal, are not sufficient to provide statutory nature to the mammals. Such differences also do not provide “new” mammals for art purposes either, as the silent changes do not affect function of the mammal..

Appellant argues the clone will always be younger than the parent, making the clone a time-delayed copy of the parent a characteristic markedly different from any prior known mammal (Brief, page 27, parag. 1). Appellant argues the time delay nature of the clone permits maintanence of the genomic material of a mammal beyond its natural lifetime (Brief, page 27, parag. 2, lines 4-7). Appellant argues maintanence of genomic material is not a trivial difference between a clone and the donor mammal and the difference cannot be ignored (Brief, page 28, lines 4-7). This difference appellant argues renders the donor mammal as not anticipating the clone (Brief, page 28, line 7-8). Appellant argues the clone is also nonobvious over its parental done mammal because the clone is time delayed (Brief, page 28, parag. 1, lines 1-2). Appellant argues the clone will always be younger than the parental mammal, a difference that could not have been expected from the prior art mammal because prior to appellant's invention a clone of a pre-existing mammal could not have existed (Brief, page 28, parag. 1, lines 4-6). Appellant argues that prior to the claimed invention the production of a clone of a pre-existing, non-embryonic donor mammal was not thought possible (Brief, page 28, parag. 1, lines 7-10). Appellant argues the unexpected result of cloning precludes a

finding of obviousness (Brief, page 28, parag. 1, lines 10-11). Appellant argues a non-living a copy is likely an obvious derivation but a living mammal would not be obvious because mammals lives for a fixed time period and whose offspring do not contain the same genetic complement due to sexual reproduction (Brief, page 28-29, bridg. sent.). These arguments are not persuasive.

Age alone cannot be a determining factor in the patentably of cloned mammals over pre-existing nuclear donor mammals. In a side-by-side comparison of a fourteen-year-old cloned cow and a fifteen year old nuclear donor cow, an age difference would not be discernable. Even in situations where an age difference can be discerned such as a one year old cow and a five-year-old cow, there is nothing novel or nonobvious between the mammals based on age. First off, the five-year-old cow was one year old, albeit four years earlier, so having been one year old is an inherent feature. However, importantly, there is no novel or nonobvious feature, characteristic or phenotype found in the younger animal. The specification does not teach age as an immutable characteristic that imbues patentable distinction. Likewise "time delayed copy" does not impart a structural feature to the clone versus the donor mammal.

"Genomic maintenance" is not defined by the specification. Appellant's meaning is not clear. Does the entire sequence of genome need to be maintained? How much variation can be tolerated for the "genome to be maintained?" The reader of Appellant's specification would not know what is meant by "maintenance of genomic material." All mammals maintain genomic material.

35 U.S.C. § 102/103

Appellant argues the references to Sims et al., McLaughlin et al., Prather et al. and Yong wt al. are directed to embryo cloned cattle, a process where nuclear transfer is performed using an embryonic cells as the nuclear donor rather than a somatic cell as required by the present claims (Brief, page 29, parag. 1, lines 1-6). Appellant argues their claims require the clone be of a pre-existing, non-embryonic, donor mammal, which is not disclosed in the cited prior art (Brief, page 29, parag. 2, lines 4-5). Appellant argues the clones of the prior art are clones of embryonic cells, and not clones of non-embryonic cells as specified by the present claims (Brief, page 30, lines 1-2). Appellant argues the limitation "non-embryonic" cannot be ignored as the claims are not product by product claims (Brief, page 30, lines 3-5). Appellant argues the two animals required by the claims, the donor and the clone, have a special relationship that is not generated by the cited prior art (Brief, page 30, parag. 2, lines 3-7). Appellant argues the clones of the cited prior art are produced from embryos which in turn were produced by normal sexual mating, and thus these embryos were not genetically identical to either of its parents (Brief, page 31, lines 1-6), Appellant argues the embryo donors were destroyed during the embryonic cloning procedure (Brief, page 31, lines 6-7). Thus, the nuclear donors of the cited prior art were never "non-embryonic," they were embryonic and opposite to the claim requirements (Brief, page 31, lines 8-10). Appellant argues the cloned mammals in the prior art had two parent, not just one as the presently claimed clone (Brief, page 31, parag. 1, lines 1-3). Appellant argues the clones of the cited prior art were not clones of a single mammal, but clones of a embryo that had genetic material from two parents (Brief, page 31, parag.1, lines 3-6). The

clones of the art would not have had the same genetic complement as either of the parents (Brief, page 31, parag. 1, lines 6-8). Appellant argues the cloning methods of the cited prior art preclude the donor mammal and clone coexistence because the embryo is destroyed (Brief, page 32, parag. 1, lines 1-5). Appellant argues the presently claimed clone is produced by a method that does not require destroying the nuclear donor (Brief, page 32, parag. 1, lines 6-8). These arguments are not persuasive.

> Claims 155 is directed to "a live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs and goats."

The examiner would maintain, as discussed above and repeated here, the term "clone" implies a method of making. At the time of filing, the only means to produce a clone, whether a clone of a pre-existing, non-embryonic, donor mammal or a clone of an embryo, was by nuclear transfer. However, the true issue here is whether or not the clone and a mammal of the same species known in the art at the time of filing are indistinguishable. The examiner maintains they are not, regardless of the method of making. A clone simply does not possess any physical or structural feature that distinguishes it from any mammal of the same species produced by sexual mating, IVF, embryonic cell nuclear transfer, as in the cited prior art, or somatic cell nuclear transfer cloning. None of these methods have any identification in the resultant mammal. While the mammals may have uncontrolled phenotypic differences caused by epigenetic events, there is no evidence that there are any discernable genotypic differences. The donor nucleus does not affect the structure of the clone because the in the nuclear transfer process, the donor nucleus is reprogrammed so that it can direct develop into a

live-born mammal. The nucleus or nuclei in the live-born clone is not the same nucleus as that donated. The “non-embryonic” state of the donor mammal is not passed through to the cells of the clone. There are no identifying characteristics that define the nuclei of the clone as being derived from the nucleus of an embryonic or non-embryonic donor. The term “non-embryonic” has not been ignored; the term just plainly does not distinguish. The special relationship between the donor and the clone cannot distinguish between the clone and prior known mammal of the same species. The relationship is not structural as the clone and the donor mammal are independent entities. Additionally, destroying an embryo to produce a cloned mammal does not affect the resulting clone. There is no structural or physical feature provided to the clone when the embryo is destroyed. If you have two cows, two sheep, two goats or two pigs, and each pair has the same RFLP pattern, there is no way to determine the clone from the nuclear donor mammal. Genetic analysis by RFLP isn’t sufficient. Again, the examiner argues in a side by side comparison appellant has not provide any evidence the clone and the donor mammal can be identified as separate beings from any other mammal of the same species.

The case law supports the examiner’s rejection : "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim

is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001). Thus the claims encompass may different clones. It is maintained that at least one clone with the claimed scope will be indistinguishable from the cited prior art mammals of the same species as the clone.

The specification lacks a method through which to distinguish a clone from any other mammal of the same species. The specification does not discuss "genetic complement" or how to use the term make such a determination. "Genetic complement" refers to the chromosomal number and composition in a single cell, and not within an entire animal. "The primary information store of a cell is it genetic complement, that is, its DNA"(Develin, page 678, 16.1, line 1). Through successive DNA replications, the genetic complement of any given cell lineage can develop mutations, mutations not affecting the phenotype of the clone. These silent mutations alter the "genetic complement" of a given cell. Since the specification does not discuss "genetic complement" or provide a definition of the term, the definitions provided by the examiner are acceptable. Appellant has not offered any evidence that the "genetic complement of donor and the clone are the same.

Further, mammals of the same species can have the same DNA fragment pattern. Flisikowski shows out of 8 bovines, 3 SSCP patterns or genotypes were found for the STAT5A gene. This data shows that there were not 8 genotypes for the STAT5A gene, but 3 genotypes. Certain of the bovines shared the same STAT5A genotype: 3 bovines had genotype 1; 4 had genotype 3 and 1 had genotype 3 (Flisikowski, page 150, figure 1). The relevancy for this prosecution is by analysis of the STAT5A gene,

one could not distinguish a clone of a cow with genotype 1 from another herd member with genotype 1. Also, in analyzing mitochondrial DNA, Koehler showed several separate Holsteins having the same mitochondrial genotype (Koehler, page 249, Figure 2A). The mitochondrial DNA labeled L-5602 is indistinguishable from one another. Each sample was isolated from leukocytes of individual bovines. This data clearly shows none of the L-5602 bovines can be distinguished from one another, and could not be determined if any of these bovines were a clone of another bovine. The genetic analysis of mitochondrial DNA is insufficient in Koehler to distinguish any bovine from its herd-mate, progeny or clone. The genetic complement is not a signature of one distinct mammal. In other words, individual identity cannot be ascertained by genetic analysis if multiple mammals have the same genetic complement, which is shown by Flisikowski et al and Koehler et al. While appellant has not directly argued the declaration by Kevin Wells, filed and , the publications of Flisikowski and Koelher indicate a lack of techniques to determine the “same set of chromosomes”, see Wells declaration, parag. 8 and 33 as an example). Wells provides no opinions as to those genetic analyses to be used in determining a clone from a mammal produced by sexual reproduction, and none is in the specification. The Polejaeva declarant states in parag. 107-109 that a clone permits the preservation of a particular genomic composition. However, as shown by Flisikowski and Koehler, there is no unique genetic composition to mammals, and appellant has not provided any evidence to contradict the opinions of the declarants notwithstanding.

The use of iris pattern to identify the clone and the donor, and to separate them from other mammals of the same species is untenable. Iris patterns in human are due to epigenetic effects (Abhyankar, page 2, col. 1, parag. 3, lines 1-2). In nonhuman mammals, therefore, the reasonable expectation is that iris patterns are determined by epigenetic factors. Thus, there is no guarantee that a clone and its donor would have the same iris pattern as the iris pattern is not only a genetic determination but an epigenetic determination. Thus, iris patterns, genetically may be the same, but environmental factor, pre and post-birth, can affect iris patterns. Appellant has offered no evidence that iris pattern is known to remain the same between a clone and its nuclear donor mammal, or that at the time of filing, iris pattern was used in animal husbandry to identify specific mammals.

It needs to be noted that nowhere in the specification does appellant indicate the clone and the nuclear donor mammal can be identified by genetic analysis or any sort or by iris identification. The specification provides no guidance on determining sameness or than such is even desired. Appellant has argued post-filing various supposed method but has not established these methods as in use at the time of filing in any readily useable or apparent manner. Further, there is no evidence that at the time of filing either genetic analysis or iris identification were acknowledged in the art as means to identify the parentage of any mammal. The specification is silent when it comes to determining a clone and nuclear donor as separate entities.

Appellant argues with regard to obviousness, the standard is not whether the differences between the mammals would have been obvious, but whether the invention

as a whole would have been obvious (Brief, page 32, parag. 2). Appellant argues it was unexpected at the time of filing that a clone of a non-embryonic nuclear donor mammal could be generated (Brief, page 33, lines 2-3). Appellant argues that prior to the claimed invention, it was not considered possible to produce a clone of non-embryonic mammal, and thus the claimed mammal could not be obvious (Brief, page 33, lines 4-6). The arguments are not persuasive.

The examiner disagrees completely with Appellant's assessment. The issue is whether or not any structural features exist in the clone that distinguish it from another mammal of the same species. There is no evidence of record that the clone is nonobvious over another member of the same species. The clone behaves and functions just as any other member of the same species. There are no features that distinguish the clone from a same species mammal other than how the clone was made. Any differences are phenotypic differences caused by environmental factors – coat color, marking, crooked horns and the like. However, these phenotypic changes are not enunciated by the specification and there is no control over their appearance. Thus, the clone is obvious if not anticipated by another mammal of the same species.

With regard to the references Zinn et al., Aldrich et al., Matte et al, and Ortega-Reyes et al., appellant argues the references do not disclose exactly the claimed invention (Brief, page 33, parag. 3, lines 1-2). Appellant argues the references do not disclose a clone, and are therefore missing an element of the claim (Brief, page 33, parag. 3, lines 2-3). Appellant argues the mammals of the cited prior art were produced by IVF, which employs sexual reproduction (Brief, page 34, parag. 1, lines 1-6).

Appellant argues these mammals, as a result of sexual reproduction, could not have contained a genetic complement of either parent, but would have contained a mixture of genetic material (Brief, page 34, parag. 1, lines 6-9) Appellant argues these mammals would have only been 50% identical to either parent (Brief, page 34, parag. 1, lines 9-10). Appellant argues the claimed clone is unlike any mammal produced by process involving sexual reproduction, including mating, IVF or nuclear transfer using an embryonic cell (Brief, page 36, parag. 2, lines 1-3). Appellant argues only the claimed clone can be obtained from a single parental donor mammal, all other mammals require two parental mammals (Brief, page 37, lines 1-6). This difference allows the clone to preserve the genetic information of the parental donor mammal without dilution (Brief, page 37, lines 6-7). Appellant argues only appellant's clone will contain the same set of chromosomes as a single non-embryonic parental mammal (Brief, page 36, parag. 1m, lines 5-6). These arguments are not persuasive.

The examiner maintains there are no patentable distinctions between the claimed clone and the prior art mammals of the same species. The production of the clone, which is only possible by nuclear transfer, does not provide any structural or physical features that distinguish the clone from any other member of the same species. Having one parent, as the clone does, or two as the IVF mammals do, does provide any structural to the mammals. As shown by Flisikowski et al and Koehler et al, discussed above, individual bovines, produced by sexual mating, can have the same genome structure as other bovines. This fact means sexual reproduction does not necessarily give mammals with distinct genomes, as Flisikowski and Koehler clearly demonstrates.

Given this one could not distinguish a clone from its nuclear donor or a sexually reproduced herd-mate. Looking at Flisikowski's Figure 1, no determination on how the bovines were produced can be made. Appellant's arguments imply that every mammal has a distinct genome, but the art of Flisikowski et al and Koehler et al show this is not accurate. Can a genome be analyzed to the extent any difference is made apparent? Perhaps, but the specification does not disclose any means to identify clones from sexually reproduced mammals. Further, show one begin to analyze the clone, a finding may occur that shows differences between the clone and the donor mammal. With each round of cell division in the clone, the changes increase of a mutation that alters the DNA sequence. Even identical twins are not regarded as possessing "identical genomes," "same genome" or being "genetically the same" (Bourchard, page 237, col. 1, parag. 2, lines 5-10). Therefore, a clone will not necessarily be identical to the donor mammal or have the same set of chromosomes as the nuclear donor, and thus genetic analysis cannot be relied upon to determine if a particular has been produced by nuclear transfer or sexual reproduction.

it is pointed out that the term "same set of chromosomes" is not defined in the specification, and is subject to several interpretations. Same set of chromosomes can mean the same number of chromosomes, such 60 chromosomes for cows. It can mean the very same set, but this is unlikely given the replication necessary in tissue growth. It can mean the same nucleotide sequence in total, with no variation, not one nucleotide difference. "Same set of chromosomes" can also mean to the same gene set such genes encoding amylase, hormones etc. Appellant meaning is not clear. Further,

Appellant does not state how one would determine the same set of chromosomes present in a donor mammal and a clone, or how one would know when two animals had the same set of chromosomes.

Appellant argues a live-born clone of a pre-existing, non-embryonic, donor mammal as claimed is a time-delayed, inexact copy of a non-embryonic donor mammal (Brief, page 34, parag. 2, lines 1-2). Appellant argues this sets them apart from all the mammals in the prior art (Brief,, page 36,. parag. 1, lines 1-3). Appellant argues the clone is an inexact copy of the pre-existing parental donor mammal, and has the same genetic complement as the parental donor mammal (Brief, page 36, parag. 1, lines 3-5). Appellant argues the claims require two animals, a pre-existing, non-embryonic donor mammal and clone of that donor mammal, and this limitation is missing from the cited prior art (Brief, page 34, parag. 2, lines 3-6). These arguments are not persuasive. The age difference between the clone and the nuclear donor mammal does not provide patentable distinction. Any mammal that is younger than another mammal will possess the age difference. However, the older mammal will anticipate the younger mammal in that the older mammal would have had to be the age of the younger. It is accepted that art disclosing the older mammal inherently discloses the older mammal at younger ages. A five year-old cow inherently was one year-old. Thus the difference in age does not provide patentable distinction as there is no structural feature that separates the older mammal from the younger clone.

Appellant's analysis of the claims is in error. The claims are drawn to a clone. The claim is analogous to a recombinant protein. The recombinant protein would only

be patentable over the same protein defined as from a specific tissue source if the recombinant protein was shown to have structural differences that distinguished the two proteins. These differences can be in activity levels, half-life, post-translational modifications or the like, but the proteins cannot be identical in structure or function. The same is applied the present claims. The clone cannot have the same structure and function as the donor mammal. Appellant has not shown clones to be different, and the claims are not directed to clones having a different structure or function from wild-type mammals.

Appellant argues at the time of filing there was no reasonable expectation of success in producing a live-born clone of a pre-existing, non-embryonic, donor mammal, as the art doubted the possibility (Brief, page 35, parag. 1). This argument is not persuasive.

The issue is not that the art doubted the method of making. The issue is if the clone is structurally and functionally identical to other mammals of the same species. The clones of the claim have no such distinguishing structures or functions as none are pointed out in the art or acknowledged in the art. Just as the recombinant protein needs to be structurally and functionally distinct from the tissue-source protein, the clone has to be structurally and functionally distinct from other mammals of the same species. The recombinant protein was doubted prior to its production, but once produced is has to be distinguished from the known protein.

Appellant argues the previous BPAI decision, January 30, 2008, stated claims to rats and horses were not anticipated or obvious over previously cited references, stating

"the Examiner has not relied on any evidence that a horse or rat having the same nuclear genetic code as a previously existing horse or rat existed or was enabled prior to Campbell's disclosure," and argues the cited prior art does not teach such either (Brief, page 35, parag. 2).

The art of Flisikowski et al and Koehler et al provide evidence showing that sexually produced mammals have the same genetic code as indicated by DNA fragment (RFLP) analysis.

Appellant argues, with regard to the Examiner's question how to determine if a mammal was produced by mating or nuclear transfer, 1) that this is improper for an art analysis but is an infringement question; 2) the claims are not product by process with the requirement only being that the mammal is a clone;. and 3) a clone could be distinguished from a progeny by comparing DNA of the progeny to the parent animals, only the clone would have the same genetic complement as its parents, that is the nuclear donor (Brief, page 36, lines 2-11). These arguments are not persuasive.

An analysis under 35 U.S.C. § 102 or 103, especially with regard to inherency or product by process, is similar to that of infringement as far as the examiner can tell. If you have two products, one in the claims and one in the prior art, you need to be able to tell a difference between them for patentability. Otherwise, the Appellant would be given proprietary rights to a product that belongs to the public. As argued above, the term clone implies a method of production as a cloned mammal can only be made by one method, nuclear transfer. Evidence and arguments provided above indicate comparing

DNA of mammals would not indicate which animal is a clone as sexually produced mammals can have the same result from DNA fragment analysis.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Deborah Crouch/
Primary Examiner, Art Unit 1632

Conferees:

/Peter Paras, Jr./
Supervisory Patent Examiner, Art Unit 1632

/Jean C. Witz/
Primary Examiner, TC1600